MDMA MEDICAL DEVICE MANUFACTURERS ASSOCIATION

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By Hand Delivery

Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

RE: Proposed Rule on Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices [Docket No. 98N-0222]

Dear Sir or Madam:

On June 18, 1998, the Food and Drug Administration ("FDA") published in the *Federal Register* a proposed rule to implement Section 401 of the Food and Drug Administration Modernization Act ("FDAMA"). Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices, 63 Fed. Reg. 31143 (June 8, 1998). Although we believe that the abbreviated 45-day comment period provided in the notice is insufficient for the proper consideration of such a significant policy, the Medical Device Manufacturers Association ("MDMA") is pleased to provide the following comments to the FDA regarding the proposed rule.[1]

Section 401 of FDAMA is a carefully crafted legislative compromise that is intended to facilitate the distribution of balanced, scientifically sound information on new uses of approved medical products. In developing the provision, Congress carefully considered the appropriate standards for the type of information that may be disseminated by the manufacturers of such products, the means by which the

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[1] *MDMA is a national trade association representing 130 independent manufacturers of medical devices, diagnostic products, and health care information systems. MDMA seeks to improve the quality of patient care by encouraging the development of new medical technology and fostering the availability of beneficial innovative products to the marketplace.*

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information may be disseminated, and the appropriate role for the FDA in overseeing the dissemination. Unfortunately, in its proposed rule, the FDA is attempting to go beyond the authority conferred upon it by Congress, proposing additional requirements that fly in the face of the intent of Section 401.

One provision of the proposed rule in particular greatly concerns the members of MDMA. Section 401 provides that manufacturers may only disseminate studies concerning a new use of an approved device if the manufacturer has submitted a "supplemental application" for such use, has met specified requirements with regard to certifying an intention to submit such a supplemental application, or has received an exemption from submitting a supplemental application from the FDA. Federal Food, Drug and Cosmetic Act § 554(a), 21 U.S.C.A. § 360aaa-3(a). In its proposed rule, the FDA has defined "supplemental application" to include a supplement to support a new use to an approved new drug application, a supplement to an approved biologics license application, a supplement to an approved medical device premarket approval application ("PMA"), and, "for devices that are the subject of a cleared 510(k) submission, a new 510(k) submission to support a new use . . . ." 63 Fed. Reg. at 31156 (proposed 21 C.F.R. § 99.3(j)). ***PMAs covering new uses for devices that are the subject of a cleared 510(k), however, are not included in the definition of "supplemental application."***

In the preamble to the proposed rule, the FDA provides the following explanation for the exclusion:

> FDA is proposing to include new 510(k) submissions as "supplemental applications" because there are no "supplements" for a new use to a 510(k) submission; instead, a new use is the subject of a new 510(k) submission. There are instances when a new use for a 510(k) device would require the submission of a PMA, but this would not be the equivalent of a "supplement" and thus, has not been included in the definition. Manufacturers that would be required to submit a PMA for a new use of a device cleared under section 510(k) of the act (21 U.S.C. 360(k)) would not be eligible to disseminate materials under the provisions of section 551 of the act.

63 Fed. Reg. at 31145-46.

There is absolutely no evidence suggesting that Congress intended to limit the application of Section 401 to exclude such new uses of 510(k) devices. The requirement that manufacturers pursue a "supplemental application" was included to address FDA's concern that allowing dissemination could eliminate the incentives for manufacturers to pursue FDA approval of new indications. It was not intended to undermine the overall purpose of the legislation—to help ensure that up-to-date, scientifically sound information on new medical therapies is made available to health care practitioners. The inclusion of PMAs for new uses of 510(k) devices in the definition of "supplemental application" would have no impact on incentives to pursue FDA approval, but their exclusion would undoubtedly frustrate the general intent of Congress.

Unless the FDA can clearly justify this exclusion based upon the congressional intent underlying the requirement to pursue FDA approval for the new use—and not simply a technical interpretation of what constitutes a "supplemental application"—the exclusion must be deleted from the final rule.

Very sincerely yours,

Stephen J. Northrup
Executive Director
Medical Device Manufacturers Association

cc: The Honorable James Jeffords
The Honorable Bill Frist
The Honorable Connie Mack
The Honorable Tom Bliley
The Honorable Joe Barton